

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 21-241V

UNPUBLISHED

JANICE LENT,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: July 11, 2024

Jeffrey S. Pop, Jeffrey S. Pop & Associates, Beverly Hills, CA, for Petitioner.

Parisa Tabassian, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT¹

On January 7, 2021, Janice Lent filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the “Vaccine Act”). Petitioner alleges that she suffered a shoulder injury related to vaccine administration (“SIRVA”) caused by an influenza (“flu”) vaccine administered on October 16, 2019. Petition at 2. The case was assigned to the Special Processing Unit of the Office of Special Masters.

For the reasons set forth below, I find that Petitioner is entitled to compensation.

¹ In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

I. Relevant Procedural History

On February 15, 2023, Respondent filed a Rule 4(c) Report opposing compensation. ECF No. 30. Specifically, Respondent argues that Petitioner cannot meet the severity requirement of the Vaccine Act, and that the medical records do not reflect onset of shoulder pain within 48 hours of vaccination. *Id.* at 9 – 11. On April 11, 2023, Petitioner was ordered to submit a Motion for a Ruling on the Record, as well as any additional information addressing issues raised in Respondent’s Rule 4(c) Report.

Petitioner did so on July 12, 2023. ECF No. 34 (“Mot.”). Respondent opposed the motion on August 14, 2023, reiterating the arguments set forth in the Rule 4(c) Report. Respondent’s Response to Petitioner’s Motion for Ruling on the Record (“Opp.”), ECF No. 35. Petitioner filed a reply on August 22, 2023. Petitioner’s Reply Brief in Support of Petitioner’s Motion for Ruling on the Record and Brief in Support of Damages (“Reply”), ECF No. 36. The matter is ripe for resolution.

II. Petitioner’s Medical Records

Petitioner’s past medical history includes no reports of left shoulder issues. Amended Petition at 1. On October 16, 2019, Petitioner received the flu vaccine in her left shoulder at the Federal Occupational Health Unit. Ex. 2.

On October 25, 2019, Petitioner had an annual physical exam with Amanda Bridges, CRNP. Ex. 3 at 13 – 16. There was no mention of left shoulder pain at this time. *Id.* at 14.

On November 1, 2019, Petitioner went to the Forrestal Occupational Health Unit with complaints of left shoulder pain. Ex. 12 at 7. Petitioner informed the health care provider that the pain had been consistent since receiving her vaccination on October 16, 2019. The provider noted that Petitioner refused administration of ibuprofen, aspirin or acetaminophen, as well as application of the “RICE” protocol (Rest, Ice, Compression and Elevation). *Id.* at 8. Petitioner was advised to take Tylenol or ibuprofen at home, apply heat and follow up with urgent care or primary care physician. *Id.* at 9. A formal incident report was prepared.

On November 5, 2019, Petitioner’s contacted her primary care provider reporting left shoulder pain. Ex. 3 at 10. The record states Petitioner said she was experiencing “pain in left shoulder after flu shot” given “around 10/24/19.” *Id.* A treater found Petitioner to have “dysfunction of left rotator cuff”. *Id.* at 11. Petitioner was referred to physical therapy, scheduled for an MRI, and a 3 week follow up appointment. The MRI was

performed on November 6, 2019. Ex. 4. Petitioner was found to have “tendinosis of the supraspinatus infraspinatus and subscapularis tendons” and a “mild acromioclavicular osteoarthritis with slight joint hypertrophy”. *Id.* at 6.

Petitioner later filed a VAERS report on November 14, 2019. Ex. 13. The report states that Petitioner received a vaccine on October 16, 2019, that the adverse event started on October 17, 2019, and that “her left arm still hurt 2 weeks following the vaccine.” *Id.* at 3-4.

Petitioner had three physical therapy visits between November 22, 2019, and December 13, 2019. Ex. 5. Charles Cocke, DPT, noted that Petitioner had “been doing her [home exercise program] and feels her shoulder is improving with less pain,” and that she was tolerating treatments well, although she was still having difficulty with some everyday tasks including washing hair and getting dressed. *Id.* at 2.

In her affidavit, Petitioner states that along with “difficulty” taking time off work, using her sick hours had a “monetary value” and would be added to her retirement fund upon retirement. Ex. 1 at 3, Ex. 15 at 3. Because of this, Petitioner decided to stop attending her appointments and preform her therapy at home. Ex. 15 at 3. From January through April 2020, due to cost expenses and the COVID-19 Pandemic, Petitioner continued to perform her at-home shoulder exercises with relief of her shoulder pain. *Id.* at 3.

On April 24, 2020, Petitioner had a televisit appointment with a treater for “continued left shoulder pain.” Ex. 6 at 4. Petitioner was noted to have full range of motion in her shoulder although no physical examination took place. *Id.* The record states that Petitioner’s left shoulder “[i]mproved completely with PT. [T]hen a few days ago, symptoms returned.” Petitioner stated in her affidavit that she informed the treater that her shoulder felt “significantly better for approximately two (2) weeks,” but pain returned when she stopped preforming the exercises. Ex. 1 at 3 – 4.

On October 14, 2020, Petitioner had a follow-up appointment for a non-related issue and received her yearly flu shot in the left arm. Ex. 6 at 2 -3. There were no reports of any pain in the left shoulder from this vaccination.

III. Fact Findings and Ruling on Entitlement

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). In addition to requirements concerning the vaccination received, the

duration and severity of petitioner's injury, and the lack of other award or settlement,³ a petitioner must establish that she suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. Section 11(c)(1)(C).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of an influenza vaccine. 42 C.F.R. § 100.3(a)(XIV)(B). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:

- (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
- (ii) Pain occurs within the specified time frame;
- (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
- (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g., NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10).

A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally

³ In summary, a petitioner must establish that she received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of her injury for more than six months, died from her injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for her injury. See § 11(c)(1)(A)(B)(D)(E).

contemporaneous to the medical events.” *Cucuras v. Sec’y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec’y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, the Federal Circuit has recently “reject[ed] as incorrect the presumption that medical records are always accurate and complete as to all of the patient’s physical conditions.” *Kirby v. Sec’y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021). Medical professionals may not “accurately record everything” that they observe or may “record only a fraction of all that occurs.” *Id.*

Medical records may be outweighed by testimony that is given later in time that is “consistent, clear, cogent, and compelling.” *Camery v. Sec’y of Health & Hum. Servs.*, 42 Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec’y of Health & Hum. Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec’y of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec’y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A. Severity Requirement

The first issue to be resolved is whether Petitioner has demonstrated that she suffered “residual effects or complications of [the injury alleged] for more than six months after the administration of the vaccine,” as required for eligibility under the Vaccine Program. Section 11(c)(1)(D)(i).

There is no dispute that Petitioner received the flu vaccine on October 16, 2019. Therefore, she must demonstrate by preponderant evidence that her residual symptoms continued at least through April 16, 2020 (assuming onset of pain the day of vaccination). *See, e.g., Herren v. Sec’y of Health & Human Servs.*, No. 13-100V, 2014 WL 3889070, at *2 (Fed. Cl. Spec. Mstr. July 18, 2014); *see also Hinnefeld v. Sec’y of Health & Human Servs.*, No. 11-328V, 2012 WL 1608839, at *4-5 (Fed. Cl. Spec. Mstr. Mar. 30, 2012) (dismissing case where medical history revealed that petitioner’s injury resolved less than two months after onset).

The record establishes that Petitioner’s initial treatment occurred between November and December 2019. Ex. 5. After her last physical therapy appointment on December 13, 2019, Petitioner next mentioned shoulder pain on April 24, 2020, stating

that her pain improved but had returned when she stopped performing her exercises. Ex. 6 at 4, Ex. 1 at 3 – 4.

Respondent argues that Petitioner did not seek treatment for her shoulder after December 13, 2019, and that it had “completely improved” by April 2020. Opp. at 6-7. However, as stated above, there are references to continued sequelae from Petitioner’s SIRVA through at least April 23, 2020. Further, the record from April 24, 2020, states that Petitioner sought care for “*continued* left shoulder pain” (emphasis added), indicating that her shoulder had not completely improved. Ex. 6 at 4.

The overall record thus constitutes a sufficient, albeit close, showing of severity to meet the evidentiary standard. It is likely that Petitioner’s symptoms persisted throughout the winter of 2020 and through the six-month deadline, despite the cessation of formal treatment and subsequent gap. However, the consistently light history of treatment suggests a mild injury - which will likely impact damages in this case.

B. Factual Findings Regarding a Table SIRVA

After a review of the entire record, I find that a preponderance of the evidence demonstrates that Petitioner has satisfied the QAI requirements for a Table SIRVA.

1. Petitioner Had No Prior Left Shoulder Condition or Injury that would Explain her Symptoms

The first requirement for a Table SIRVA is a lack of problems associated with the affected shoulder prior to vaccination that would explain the symptoms experienced after vaccination. 42 C.F.R. § 100.3(c)(10)(i). Respondent does not dispute that Petitioner meets this criterion. I find that she has demonstrated a lack of history of pain, inflammation, or dysfunction of her left shoulder that would explain her symptoms.

2. Onset of Petitioner’s Injury Occurred within Forty-Eight Hours of her Vaccination

The medical records preponderantly establish onset of injury close-in-time to vaccination. Petitioner first reported shoulder pain sixteen days after her November 1, 2019, vaccination, stating that she had shoulder pain following her flu vaccine. Ex. 12 at 7. Thereafter, she consistently linked her shoulder pain to the flu shot. See Ex. 3 at 10 (record from November 5, 2019 stating that Petitioner had pain in her left shoulder after a flu shot); Ex. 13 at 3-4 (VAERS report stating that Petitioner’s adverse event started on October 17, 2019).

Respondent argues that Petitioner inconsistently reported the vaccination date as October 16, “which suggests the onset of her symptoms may have been on or about October 24, 2019. Opp. at 11. Further, Petitioner failed to report shoulder pain when she had a physical exam on October 25, 2019. *Id.* Even so, a finding of proper onset can be made based on such a record. Program petitioners are not required to marshal records setting forth with chronographic specificity the precise day and hour that their onset manifested. As noted above, Petitioner consistently linked her shoulder pain to the October 16, 2019, flu vaccine.

Additionally, the relevant medical records show that Petitioner reported shoulder pain in a relatively timely manner, when measured from the date of vaccination. Thus, Petitioner first began to complain of shoulder pain within fifteen days of the vaccine and did not attribute her pain to any other injury or cause. It is common for SIRVA petitioners to delay seeking treatment, thinking the injury will resolve on its own, especially since patients are often told by medical providers at the time of vaccination to expect some soreness and pain for a period of time after. And individuals also often misconstrue the nature of their injury, and therefore fail to inform treaters of all specific facts relevant to onset until later. Here, the added detail of onset did not “wait” for months before being provided but began to be reported in a reasonable time post-vaccination. And Petitioner affirmatively and repeatedly linked her shoulder pain to the flu vaccine. Further, it is not unexpected that Petitioner did not raise her shoulder pain with NP Bridges on October 25, as that appointment was for a specific and unrelated issue, *i.e.*, migraines. Ex. 3 at 13.

Accordingly, there is preponderant evidence that establishes the onset of Petitioner’s left shoulder pain more likely than not occurred within 48-hours of vaccination.

3. Petitioner’s Pain was Limited to her Left Shoulder

Petitioner’s pain was limited to her left shoulder. Respondent does not contest this aspect of Petitioner’s claim, and there is nothing in the records to suggest otherwise.

4. There is No Evidence of Another Condition or Abnormality

The last criteria for a Table SIRVA state that there must be no other condition or abnormality which would explain a petitioner’s current symptoms. 42 C.F.R. § 100.3(c)(10)(iv). Respondent does not contest this aspect of Petitioner’s claim, and there is nothing in the records to suggest that any such condition or abnormality exists.

C. Other Requirements for Entitlement

In addition to establishing a Table injury, a petitioner must also provide preponderant evidence of the additional requirements of Section 11(c). Respondent does not dispute that Petitioner has satisfied these requirements in this case, and the overall record contains preponderant evidence to fulfill these additional requirements.

The record shows that Petitioner received a flu vaccine intramuscularly on October 16, 2019, in the United States. Ex. 3; see Section 11(c)(1)(A) (requiring receipt of a covered vaccine); Section 11(c)(1)(B)(i)(I) (requiring administration within the United States or its territories). There is no evidence that Petitioner has collected a civil award for her injury. Petition at 4; Section 11(c)(1)(E) (lack of prior civil award).

Based upon all of the above, Petitioner has established that she suffered a Table SIRVA. Additionally, she has satisfied all other requirements for compensation. I therefore find that Petitioner is entitled to compensation in this case.

Conclusion

In view of the evidence of record, I find that there is preponderant evidence that Petitioner satisfies the QAI requirements for a Table SIRVA. Further, based on the evidence of record, I find that Petitioner is entitled to compensation.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master